

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

All Cases)
)

**TENNESSEE CLINIC DEFENDANTS' RESPONSE TO
MOTION OF THE UNITED STATES FOR A STAY OF CERTAIN DEPOSITIONS
PENDING RESOLUTION OF RELATED CRIMINAL PROCEEDINGS**

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, A Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald Jones, MD (collectively "Tennessee Clinic Defendants") hereby *respond* to the *Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings* (hereinafter, at times, the "Motion")¹.

The United States, in its Motion, requests that the Court stay the civil depositions of former employees of NECC and MSM and of the Massachusetts Board of Pharmacy until after the NECC criminal case concludes, which is currently set for trial beginning on April 4, 2016.²

The Tennessee Clinic Defendants *do not* oppose parts of the Motion but *do* oppose other parts of the Motion, as described below.

¹ The United States' Motion is at Dkt. 2209.

² Dkt. 2009, p. 1.

1. Summary of Tennessee Clinic Defendants' position on Government's Motion

The Tennessee Clinic Defendants' position on the Government's Motion is:

Motion to stay Massachusetts Board of Pharmacy deposition:

1. The Court should deny this part of the Motion. This Court has already rejected the argument that the Massachusetts Board of Pharmacy ("MA BoP") deposition should not go forward because of the pending criminal prosecution.³ Because this issue has already been decided, in the absence of any new information or argument, the Government's Motion to Stay the MA BoP deposition should be denied.

Motion to stay depositions of former NECC/MSM employees:

2. First and foremost, the Court should *not* require the Tennessee Clinic Defendants to disclose experts or try the first civil case prior to taking the NECC/MSM depositions that the Government seeks to stay.
3. The most logical, most efficient, and least prejudicial relief (and the relief that the Tennessee Clinic Defendants request) is that the Court (1) grant the Government's Motion and, at this point, stay the depositions of former NECC and MSM employees; (2) stay the Tennessee expert disclosure deadlines until after the conclusion of the criminal trial; (3) not set any trial date until after the conclusion of the criminal trial; and (4) allow the civil cases to proceed with any fact discovery *unrelated* to NECC or MSM until the criminal case concludes.
4. Alternatively, if the Court intends to push the Tennessee cases into expert discovery and the first trial before the conclusion of the criminal prosecution, the Government's Motion must be *denied*.

Consistent with the foregoing, the Tennessee Clinic Defendants respectfully request that the Court enter the proposed order attached as Exhibit 1.

³ See Dkt. 2164.

2. Procedural background relevant to this Response

a. Present deadlines

The following common discovery deadlines are in place for the Tennessee Clinic Defendants⁴:

| | |
|------------------------------------|-------------------|
| Close of Common Fact Discovery | October 15, 2015 |
| Opening Common Expert Reports Due | November 16, 2015 |
| Rebuttal Common Expert Reports Due | December 14, 2015 |
| Reply Common Expert Reports Due | December 30, 2015 |
| Close of Common Expert Discovery | January 18, 2016. |

b. Status of NECC-related discovery

i. **The primary goal of discovery is to guarantee mutual knowledge of all relevant facts, to ensure a fair trial.**

Well-settled principles guide discovery in federal lawsuits:

The purpose of pre-trial discovery is to allow “parties to obtain the fullest possible knowledge of issues and facts before trial.”⁵ Discovery should remove surprise from trial preparation⁶ and allow for mutual knowledge of all relevant facts⁷. Such mutual knowledge of relevant facts is essential to proper litigation.⁸ Pre-trial discovery should be a tool in the search for truth.⁹ In overseeing discovery, the court should consider the party’s right to prepare his defense.¹⁰ These principles are intended to ensure a fair trial.¹¹

⁴ Dkt. 2251, 2251-1.

⁵ *Barr v. EQT Prod.*, No. 5:14CV57, 2015 WL 2238067, *5 (N.D. W.V. 2015) (cites omitted).

⁶ *Schwartz v. TRW, Inc.*, 211 F.R.D. 388, 392 (C.D. Cal. 2002).

⁷ *Matter of Hawaii Corp.*, 88 F.R.D. 518, 524 (D. Hawaii 1980).

⁸ *Smith v. Piper Aircraft Corp.*, 18 F.R.D. 169, 179 (M.D. Pa. 1955).

⁹ *Tiedman v. American Pigment Corp.*, 253 F.2d 803, 808 (4th Cir. 1958).

¹⁰ *See Mitchell v. Roma*, 265 F.2d 633, 636 (3rd Cir. 1959) (“[o]ne must balance the public interest in protecting the flow of information against the individual’s right to prepare his defense, taking into consideration the particular circumstances of each case”).

¹¹ *In re E.I. DuPont de Nemours & Co.*, 918 F.Supp. 1524, 1542 (M.D. Ga. 1995) (“The obvious and overall purpose of discovery under the Federal Rules is to require the disclosure of all relevant information, so that the ultimate resolution of disputed issues in any civil action may be based on a full and accurate understanding of the true facts, and therefore embody a fair and just result.”).

Unfortunately, the discovery of NECC and its affiliates in this litigation has not proceeded consistent with these well-settled principles. Instead of an open search for the truth, the search for information from and about NECC has been a multi-year effort, employing virtually every available discovery tool, all met with fierce resistance.¹² At this point, on the cusp of the close of common discovery, the Tennessee Clinic Defendants have an incomplete set of NECC documents and zero testimony from any former NECC or MSM employee they have sought to depose. This is not the open, mutual information exchange the federal rules require.

ii. The Tennessee Clinic Defendants have tried to obtain NECC-related document discovery consistently since 2013.

In September 2013, the Tennessee Clinic Defendants first requested access to NECC documents already given to the PSC.^{13 14} NECC refused. The Tennessee Clinic Defendants requested these documents again in January 2014. NECC refused again. Left with no other option, the Tennessee Clinic Defendants sought court intervention.¹⁵ The Trustee finally relented in April 2014, providing access to a repository of ~43,000 documents, documents that the Plaintiffs had unilateral access to for many months prior to the Tennessee Clinic Defendants being given access.¹⁶

¹² At times, it has felt like the Tennessee Defendants are the only parties in the Tennessee cases actually providing substantive information.

¹³ Actually, the campaign for NECC documents began in 2012, when the Tennessee Clinic Defendants (not yet defendants) made FOIA requests for NECC-related documents held by the FDA. Maybe portending a theme, the FDA objected to production of almost everything it had in its possession.

¹⁴ At the last hearing with Judge Boal, the Government made the baseless argument that the Tennessee Defendants were using discovery of NECC as some sort of tactic to stall the litigation. Hr'g Tr. 34:7-9 (September 9, 2015, status conference). This is a grossly uninformed argument. One only needs to look at the docket to see that the Tennessee Defendants' efforts at discovery of NECC and MSM began over *two years ago*. The Tennessee Defendants have maintained since 2013 that discovery of NECC and its affiliates is essential to defending the cases. To suggest that counsel would waste the Court's time and resources in an ulterior effort at delay is irresponsible, particularly when it is so far from the any reasonable interpretation of the history of these cases.

¹⁵ Dkt. 1037, 1038.

¹⁶ Hr'g Tr. 27:14-28:7 (April 10, 2014, status conference).

While this incomplete set of documents was a start, it was nowhere near the discovery needed to defend 100+ lawsuits. Thus, in March 2015 (months before any discovery deadlines), continuing the effort to obtain information and documents necessary to defend the suits, the Tennessee Clinic Defendants sent written discovery to the NECC insiders.¹⁷ This yielded virtually no information; the NECC insiders invoked the Fifth Amendment to virtually every question.¹⁸

The Tennessee Clinic Defendants also went directly to the entity responsible for the entire litigation, serving written discovery on NECC well before any deadline.¹⁹ The Tennessee Clinic Defendants sent 19 targeted document requests. In response to 19 targeted requests, NECC managed 21 general objections and specific objections to 19 of 19 requests.²⁰ The Trustee has refused to meet and confer on these responses, despite their obvious inadequacy.^{21 22}

Despite these diligent efforts at document discovery of NECC and its affiliates,²³ as the civil litigation nears the close of common discovery and opening expert reports, the Tennessee Clinic Defendants *still* do not have such basic categories of documents as personnel files, NECC inspection reports, and cleaning records.²⁴ The Trustee's dump of ~100,000 documents on the Tennessee Clinic Defendants is apparently about *one percent* of the nine million documents in the criminal case.²⁵

¹⁷ See, e.g., Dkt. 2195, 2196.

¹⁸ See, e.g., Dkt. 2195, 2196.

¹⁹ Dkt. 1813.

²⁰ Dkt. 1813.

²¹ Dkt. 2190, 2191.

²² Despite this incessant refusal to provide the Tennessee Clinic Defendants with the meaningful discovery they need, notably, *no one* has made a credible argument that the information and testimony they seek from NECC and its affiliates is not discoverable, relevant, and important. That point seems conceded.

²³ Written discovery has also been sent to all NECC affiliates, with similar results. See, e.g., Dkt. 1772.

²⁴ Dkt. 2190, 2191.

²⁵ See Dkt. 2209, p. 2 (noting 8.8 million documents in the NECC criminal discovery).

iii. The Tennessee Clinic Defendants have likewise been rebuffed in efforts to obtain depositions of basic NECC/MSM employees.

The attempts to take *depositions* of NECC/MSM employees have been even *more* difficult than the battle to obtain responsive *documents*.

The Tennessee Clinic Defendants, in April 2015, first tried corporate notices to NECC and its affiliated companies.²⁶ Rather than produce a corporate representative, NECC and its affiliates²⁷ spent dozens upon dozens of hours fighting the notices.²⁸

The Tennessee Clinic Defendant also tried noticing the individual NECC owners in April 2015.²⁹ These were likewise met with motions for protective orders.³⁰

The Tennessee Clinic Defendants tried, beginning in April 2015, subpoenaing lower-level employees of NECC, in hopes of building a working knowledge of what happened at NECC and its affiliates from the ground-up.³¹ Even these lower-level employees filed motions for protective order.^{32 33}

²⁶ See, e.g., Dkt. 1782.

²⁷ The fervor with which they have refused to participate in discovery is surprising given that NECC is bankrupt and non-functional, and its affiliates are all non-functioning, and none face any further liability. One would think that the most efficient, cost-effective way to handle this for the estate would be to freely provide documents and information, rather than spend thousands of dollars from the estate to fight providing relevant information.

²⁸ See, e.g., Dkt. 1810.

²⁹ Dkt. 1773.

³⁰ See, e.g., Dkt. 1823.

³¹ See, e.g., Dkt. 1782-4.

³² See, e.g., Dkt. 2211.

³³ Efforts to obtain documents from the MA BoP have been equally as frustrating. The Tennessee Clinic Defendants sent their first request to the MA BoP for documents related to NECC in October 2012. It netted *three pages* of documents. Re-requests, letters, conferences, and motions have yielded thousands more documents and permission to depose a corporate witness.

As a result of the wall of silence from NECC, its affiliates, and the individual employees, virtually all of the 2015 spring and summer was spent responding to motions for protective orders. Following extensive motion practice, the Court set the parameters on what depositions were allowed and not allowed, basically allowing depositions of *unindicted* NECC/MSM employees and of the MA BoP, but staying all others until the conclusion of the criminal case.³⁴ With that guidance, the Tennessee Clinic Defendants tracked down and subpoenaed about a half-dozen former NECC/MSM employees that fell within the Court's narrow category of witnesses who could be deposed.³⁵ The Tennessee Clinic Defendants also made prompt attempts to set the MA BoP deposition.

iv. The Government now moves to stay these NECC/MSM depositions.

After the Tennessee Clinic Defendants spent dozens of hours finding these witnesses, serving them with subpoenas, and scheduling and re-scheduling depositions, the Government filed the instant Motion to stay them. The Government argues that deposing former employees of NECC and MSM would jeopardize the Government's prosecution of the NECC insiders and could generate pre-trial publicity.³⁶

As summarized above:

1. If the Court feels the Government has met its burden to justify the stay, the Court should stay the depositions (with the exception of the MA BoP) but, in conjunction, should stay the MDL deadlines for expert disclosures and the trial date for the first civil trial.
2. If the Court intends to require the Tennessee Clinic Defendants to disclose experts and try the first civil case before the criminal trial concludes, the Tennessee Clinic Defendants oppose the Motion.

³⁴ Dkt. 2123.

³⁵ See Dkt. 2184.

³⁶ Dkt. 2209, p. 1-2.

3. Law and argument in response to the Government's Motion to Stay

a. The Court should deny the Motion as it relates to the MA BoP deposition.

The Government moves to stay the deposition of the MA BoP, arguing that it would jeopardize the Government's ability to prosecute the criminal case. The Government conveniently fails to mention that the Court has already rejected this exact argument.³⁷

At Dkt. 1975, the MA BoP, with the support of the U.S. Attorney's Office, moved to postpone the deposition of the MA BoP until after the criminal case.³⁸ The MA BoP submitted an affidavit of the U.S. Attorney to support the motion.³⁹ The MA BoP and U.S. Attorney made the same arguments that the U.S. Attorney makes here, *i.e.*, that the deposition of the MA BoP would impair the criminal prosecution.⁴⁰

The Court denied the request to stay, finding, in part, that the MA BoP is not part of the criminal prosecution, but is "simply a potential witness in the Criminal Case."⁴¹

The Government offers no reason here that the Court's prior decision on the same issue should be revisited.⁴² The Government simply duplicates the argument that the Court rejected 60 days ago. This issue has already been decided. The Court should deny the Government's Motion to Stay as it relates to the MA BoP deposition.

³⁷ See *In re de la Madrid*, 534 B.R. 7, 16 (D. P.R. 2014) ("[t]he 'law of the case' doctrine 'makes binding upon a court a ruling made [in] the same...level [of court] during prior stages of the same litigation'") (citing *Lacy v. Gardino*, 791 F.2d 980, 984 (1st Cir. 1986)).

³⁸ Dkt. 1975.

³⁹ Dkt. 1975.

⁴⁰ Compare Dkt. 1976, p. 2 ("[s]uch a deposition, prior to the trial of the criminal case,...could require the early disclosure of the elements of the government's case-in-chief; and could generate substantial pretrial publicity that might unnecessarily prejudice all parties' rights to a fair criminal trial before an impartial jury") with Dkt. 2209, p. 2 ("[the MA BoP deposition] would jeopardize the government's ability to prosecute the criminal case by allowing civil litigants, including possibly defendants in the criminal case, to depose, months before the criminal trial, several of the government's potential trial witnesses...[and] if allowed to proceed, [the MA BoP deposition] could generate substantial pretrial publicity that could affect the rights of the fourteen criminal defendants to a fair trial").

⁴¹ Dkt. 2123.

⁴² Curiously, at p. 9 of the instant Motion, the Government cites Judge Boal's order on the FDA's motion for protective order, but conveniently omits mention of the order on the MA BoP's motion.

b. If the Court grants the Government's Motion to Stay the depositions of the NECC/MSM employees, it must also stay expert discovery and not set any civil trial until after the criminal trial.

If the Court grants the Government's Motion and stays the depositions of the NECC/MSM employees until after the conclusion of the criminal case, it must likewise (1) stay expert discovery in the civil cases until after the criminal case concludes (so as to allow for the NECC/MSM employee depositions prior to expert discovery) and (2) not set any civil trial until after the criminal case and the NECC/MSM employee depositions.⁴³

Two reasons dictate this course:

First, to require the Tennessee Clinic Defendants to engage in expert discovery and try the first civil case before the conclusion of the criminal case and the NECC/MSM employee depositions would be extremely prejudicial to the Tennessee Clinic Defendants.⁴⁴

Second, to conduct expert discovery and a civil trial prior to the NECC/MSM employee depositions would be very wasteful. A civil trial on an incomplete factual record and without a fair presentation of the defenses is a waste of time and money and yields an unrepresentative verdict.

⁴³ Practically speaking, it should also be noted that the Middle District of Tennessee, in the Specialty Surgery Center declaratory judgment action, is in the process of certifying a question for the Tennessee Supreme Court regarding the viability of the Plaintiffs' product liability claims against Specialty Surgery Center. See Order, Honorable Joe Brown, United States Magistrate Judge, in M.D. Tenn., No. 2:15-cv-00026, Dkt. 77 (9/23/15). Briefing, argument, and a decision on the issue are unlikely to be completed before the criminal trial begins in April 2016. As this Court noted in its decision on the Tennessee Clinic Defendants' motion to dismiss, this is an undecided issue under Tennessee law and needs to be resolved before a civil trial can occur. Dkt. 1360 pp 29-31.

⁴⁴ This prejudice is discussed below and also attested to in the affidavit C.J. Gideon, Jr., lead trial counsel for the Tennessee Clinic Defendants, attached as Exhibit 2.

- i. **Requiring the Tennessee Clinic Defendants to engage in expert discovery and a trial prior to the NECC/MSM employee depositions would be extremely prejudicial to the Tennessee Clinic Defendants because these witnesses hold information essential to the defense of the cases.**

The testimony of former NECC and MSM employees is essential to the Tennessee Clinic Defendants' affirmative defenses (e.g., comparative fault and intervening cause) and non-affirmative defenses (e.g., compliance with the standard of care). Because these witnesses hold relevant information essential to defenses, forcing the Tennessee Clinic Defendants to litigate these cases through trial without this testimony is tantamount to striking certain defenses and eliminating certain facts from the trial. It would prejudice the Tennessee Clinic Defendants through no fault of their own.

(1) Requiring the Tennessee Clinic Defendants to litigate these cases through trial without depositions of NECC and MSM all but eliminates the opportunity to defend these cases by arguing the fault of NECC and MSM.

The Tennessee Clinic Defendants have asserted as an affirmative defense the comparative fault of NECC and MSM.⁴⁵ To establish NECC or MSM's comparative fault, the Tennessee Clinic Defendants are required to *prove* the fault of NECC or MSM at trial, bearing the burden just as if they were plaintiffs.⁴⁶ If the jury finds that NECC or MSM were at-fault and caused injury to the Plaintiffs, the jury will be instructed to allocate a percentage of the overall fault to NECC/MSM, reducing the liability that may be allocated to the Tennessee Clinic Defendants if they are found to be at-fault.⁴⁷

⁴⁵ Dkt. 1455, Answer to Master Compl., p. 67-77.

⁴⁶ See *Carroll v. Whitney*, 29 S.W.3d 14, 21 (Tenn. 2000) (holding that defendant asserting the fault of a non-party has the burden to prove the non-party's fault before the jury can allocate fault to it); see also *Stanfield v. Neblett*, 339 S.W.3d 22, 29 (Tenn. Ct. App. 2010) ("[i]n his answer, Dr. Neblett asserted the defense of comparative fault of the hospital and nursing staff. Accordingly, Dr. Neblett bears the burden of proving comparative fault").

⁴⁷ See *Hall v. Derrick*, No. W2003-01353-COA-R3-CV, 2004 WL 2191016, *4 (Tenn. Ct. App. 2004) (noting that, once it is determined two parties were negligent, the trier of fact must allocate the percentage

No reasonable person can argue that the testimony of NECC and MSM employees is not necessary to establish the fault of NECC and MSM. What trial lawyer would (or could) prove the fault of a party without taking the depositions of the party or its actors? It is essential.⁴⁸

The PSC disingenuously argues that the Tennessee Clinic Defendants should simply proceed to trial bearing the burden to establish the fault of NECC and MSM *without* any witness testimony. If the PSC believes witness testimony is unnecessary to prove fault, it should likewise be barred from presenting live testimony in its case against the Tennessee Defendants.⁴⁹ The PSC should not be permitted to advocate for draconian limitations on the form of evidence available to the Tennessee Clinic Defendants at trial if the PSC is unwilling to be bound by those same limitations.

of fault) (cites omitted). For instance, if the jury rendered a \$500,000.00 verdict and assigned fault as 90% NECC and 10% the Tennessee Clinic Defendants, the Tennessee Clinic Defendants would only be responsible for a \$50,000.00 judgment. The other \$450,000.00 would be uncollectible.

⁴⁸ It bears noting here that the Government apparently has a fundamental misunderstanding of comparative fault law in Tennessee. At p. 5, note 8 of the motion, it states: “[I]t is unclear why the St. Thomas Entities believe they need (or would even want) to do more than establish that NECC sold them contaminated methylprednisolone acetate, which no one to date has disputed, for their comparative fault claim against NECC.” Such a stipulation would give the Tennessee Defendants *nothing* because they bear the *burden of proving, affirmatively, the fault of NECC, i.e., duty, breach, causation, and damages*. A factual stipulation that NECC manufactured the drug does not establish the comparative fault defense. In fact, it establishes not one element of the defense. It also ignores the fact that the jury must make a *quantitative* determination of the percentage of fault attributable to NECC/MSM. *Persuasive* proof (e.g., witness testimony) is necessary to convince a jury of the appropriate *amount* of fault attributable to NECC/MSM. No jury would find persuasive a stipulation that simply stated that NECC sold contaminated medication.

⁴⁹ The Government also argues that the Tennessee Defendants have sufficient evidence to prove its defenses and do not need witnesses. One imagines the Government also would likely not be keen on having to prove its case against NECC and MSM without any live witnesses.

It is close-to-impossible to prove that NECC and MSM acted negligently and caused injury to the Plaintiffs without taking testimony of (at least some of) the persons involved in the allegedly negligent acts. To so limit the Tennessee Clinic Defendants – to require them to prove the fault of NECC and MSM without any witness testimony – is commensurate to simply eliminating that defense, which is plainly prejudicial.

(2) MSM and NECC employees also hold information necessary for the Tennessee Clinic Defendants’ non-affirmative defenses to the complaints.

The testimony of these witnesses is likewise indispensable to numerous issues relevant to defense of the claims of the complaint *other than* comparative fault.⁵⁰ For instance:

- The Plaintiffs allege that the standard of care required a site visit of NECC prior to purchasing from it.⁵¹ The Defendants’ position is that (1) this was not required and (2) even had they done a site visit, it would have revealed nothing to deter them from buying product from NECC. The testimony of NECC employees is essential to establish what the facility looked like in 2011-12 to demonstrate that a site visit would have revealed nothing that would have led the Defendants to purchase from another company.
- The Plaintiffs allege that the standard of care required certain due diligence by the Tennessee Clinic Defendants before buying from NECC.⁵² The Tennessee Clinic Defendants need to depose NECC and MSM employees responsible for interacting with customers to determine what – *if any* – customers of NECC actually did any of the due diligence that the Plaintiffs allege was “standard.”⁵³

⁵⁰ The Government takes inconsistent positions on the importance of these witnesses to the case against NECC/MSM. It argues on one hand that the witnesses are so unimportant that it cannot understand why the Tennessee Defendants would want to depose them to help their case against NECC. But, on the other hand, it argues that the witnesses are so important that any revelation of their testimony will sink the criminal prosecution.

⁵¹ Dkt. 545, Master Compl., ¶192.

⁵² *Id.*

⁵³ The Tennessee Clinic Defendants tried to obtain this information via a 30(b)(6) deposition of NECC. The Court did not allow that. The Tennessee Clinic Defendants tried it via document requests to the Trustee. The Trustee refused. The Tennessee Clinic Defendants also tried to obtain the information via request for admission to the PSC. They likewise refused to answer. The Tennessee Clinic Defendants tried to obtain a stipulation from the PSC to obtain it via deposition by written question. The PSC refused. This may be the only avenue left to obtain this crucial information.

- The Plaintiffs allege that, had the Tennessee Clinic Defendants asked certain questions of NECC prior to purchasing, NECC's answers would have prompted the Defendants to purchase elsewhere.⁵⁴ The Tennessee Clinic Defendants must depose employees of MSM and NECC responsible for communicating with customers to establish that NECC's responses to the questions would have been satisfactory.
- The Plaintiffs allege that the Tennessee Clinic Defendants should have known that NECC was a traditional compounding pharmacy and not a manufacturer.⁵⁵ However, the evidence suggests that NECC operated as and represented itself to be a manufacturer of medications, such that it was entirely reasonable for a customer to treat it like a manufacturer. To establish that NECC held itself out as a manufacturer, the Defendants must depose NECC/MSM employees.
- A primary non-affirmative defense to the complaints is that the Tennessee Clinic Defendants reasonably relied on the representations of NECC and MSM that the NECC product was safe and that this was all the standard of care required. This cannot be demonstrated to the jury without the testimony of the NECC and MSM employees about representations made to customers.
- The Tennessee Clinic Defendants assert that the actions of NECC were a superseding, intervening cause of the Plaintiffs' injuries, relieving them of liability.⁵⁶ The Tennessee Clinic Defendants cannot prove that the actions of NECC were an intervening cause without taking testimony from NECC actors.⁵⁷
- Even an issue as simple as validating NECC's customer list, an important piece of evidence that establishes thousands of customers from 40+ states bought from NECC (likely without doing any of the due diligence the PSC says was standard), requires the testimony of someone at NECC or MSM.⁵⁸

* * * * *

⁵⁴ Dkt. 545, Master Compl., ¶192.

⁵⁵ Dkt. 545, Master Compl., ¶¶170-73.

⁵⁶ Dkt. 1455, Answer to Master Complaint, p. 62.

⁵⁷ See *Howell v. Turner*, No. M2008-01588-COA-R3-CV, 2009 WL 1422982, *4 (Tenn. Ct. App. 2009) (“[t]he essential factors necessary to demonstrate a superseding cause are (1) the harmful effects of the superseding cause must have occurred after the original negligence; (2) the superseding cause must not have been brought about by the original negligence; (3) the superseding cause must actively work to bring about a result which would not have followed from the original negligence; and (4) the superseding cause must not have been reasonably foreseen by the original negligent party. If all four elements are met, then the intervening cause is said to be a superseding cause which breaks the chain of proximate causation. Because the superseding cause, therefore, ‘supplants’ a defendant’s conduct as the legal cause of the plaintiff’s injuries, it relieves the defendant from liability to the plaintiff”) (cites omitted).

⁵⁸ One would assume validating this list – published by the FDA – would be easy. However, the Plaintiffs will not admit its authenticity or accuracy.

Former employees of NECC and MSM hold vital, indispensable information relevant to comparative fault defenses and non-affirmative defenses to the complaints. The Tennessee Clinic Defendants cannot fairly defend the complaints against them without the testimony. To require them to do so would cause *extreme* prejudice to the Tennessee Clinic Defendants, through no fault of their own.⁵⁹

ii. Forcing the Tennessee Clinic Defendants to disclose experts, engage in expert discovery, and move toward trial without the testimony of these NECC and MSM witnesses would be costly and inefficient.

In addition to the extreme prejudice to the Tennessee Clinic Defendants if they are forced to litigate these cases through expert discovery and trial without the testimony of the NECC and MSM witnesses, doing so would be unnecessarily costly and inefficient.

The bellwether trial process – which the Court has adopted here – is premised on the selection of a representative case for trial, to be tried and to serve as the bellwether.⁶⁰ If a non-representative case is tried, the court and lawyers waste substantial time and money.⁶¹

To try the first bellwether case without the depositions of the NECC and MSM employees – essentially trying the first case on a limited factual record without allowing the Defendants the opportunity to fully develop and present their defenses – will be a colossal waste of resources. It will yield a result that is not representative of the rest of the cases.

⁵⁹ The Government says at p. 16, note 11, that the Tennessee Defendants will not be prejudiced if they cannot depose these witnesses. As demonstrated herein, that is an entirely uninformed and incorrect statement.

⁶⁰ Fallon, *et al.*, *Bellwether Trials in Multidistrict Litigation*, 82 Tulane Law Rev. 2323, 2343 (2008).

⁶¹ *Id.* at 2344.

⁶¹ *Microfinacial, Inc. v. Premier Holidays Intern.*, 385 F. 3d 72, 74 (1st Cir. 2004).

⁶¹ *Marquis v. F.D.I.C.*, 965 F.2d 1148, 1155 (1st Cir. 1992).

Requiring the Tennessee Clinic Defendants to disclose experts without their consideration of important testimony from NECC and MSM, depose experts without the benefit of information from basic NECC/MSM fact witnesses, and defend cases at trial without the deposition testimony of NECC and MSM, will be a costly endeavor that would produce nothing but an unrepresentative, unfair, and unreliable trial verdict.

* * * * *

No reasonable argument or case citation can be offered to support the notion that the civil cases should press into expert discovery and a trial *before* the depositions of key witnesses like the NECC and MSM employees. That would be extremely prejudicial to the Tennessee Clinic Defendants and wholly inefficient. The prudent step is to suspend expert discovery and any civil trial while the criminal case proceeds and, after its conclusion, conduct the depositions of these MSM and NECC employees, conduct expert discovery, and then have a fair, representative trial on a full factual record.

Put simply, whatever relief the Court fashions in response to the Government's Motion should not require the Tennessee Clinic Defendants to disclose experts or try these cases before the NECC/MSM depositions. That option benefits no one, prejudices the Tennessee Clinic Defendants greatly, ignores the bellwether system, and creates unnecessary costs.

- c. If the Court intends to require the Tennessee Clinic Defendants to proceed with expert discovery and trial before the criminal case concludes, the Court must deny the Government's Motion and allow the Tennessee Clinic Defendants to proceed with the depositions of NECC/MSM.**

As set out above, if the Court grants the Government's Motion to Stay, it must also stay expert discovery and any trial date until the Tennessee Clinic Defendants can depose the MSM and NECC employees. However, *if* the Court is unwilling to stay the expert deadlines and civil trial date, the analysis of whether to grant the Motion fundamentally changes, and the Court *must* deny the Government's Motion and allow the depositions of the former NECC/MSM employees to proceed.

- i. If the Court plans to push the Tennessee Clinic Defendants into expert discovery and trial, the equities weigh in favor of denying the stay of NECC/MSM discovery.**

The Government correctly sets out the *Microfinancial* factors for the Court to consider in deciding on this motion to stay:

1. Interests of the civil plaintiff in proceeding expeditiously with the civil litigation
2. Hardship to the criminal defendant, including the burden placed on him should the cases go forward in tandem
3. Convenience of both the civil and criminal courts
4. Interests of third parties
5. Public interest
6. Good faith of the litigants
7. Status of the cases
8. Extent of the overlap in the criminal case and civil case.

Whether a court should impose a stay requires consideration of various interests and is a case-specific inquiry.⁶² The court must ensure that competing equities are weighed.⁶³ To obtain a stay, the movant must carry a heavy burden.⁶⁴

Here, if the Court intends to push the civil cases into expert discovery and trial before the conclusion of the criminal case, the equities weigh in favor of denying the stay. As explained above, requiring the Tennessee Clinic Defendants to defend this case through expert discovery and trial without the testimony of NECC/MSM employees is extremely prejudicial and wasteful.

ii. If the Court intends to push the Tennessee Clinic Defendants into expert discovery and trial without the NECC/MSM depositions, the Government has not met its burden to justify the stay.

When weighed against the extreme prejudice to the Tennessee Clinic Defendants and the wasted resources if a civil trial were to be held before the NECC/MSM depositions, the justifications offered by the Government do not meet the heavy burden for imposing a stay.

The Government's concern about the criminal defendants attending the depositions of these witnesses and obtaining information for use in the criminal trials is misguided.⁶⁵

MDL Order No. 10 (the Deposition Protocol) specifically states:

[D]epositions may be attended by counsel of record, members and employees of their firms, members of the Plaintiffs' Steering Committee ("PSC"), attorneys specially engaged by a party for purposes of the deposition, the parties or the representative of a party, court reporters, videographers, the deponent, and counsel for the deponent.⁶⁶

⁶² *Microfinancial, Inc.*, 385 F.3d at 77.

⁶³ Most of the *Microfinancial* factors are irrelevant here or do not tilt heavily toward either side.

⁶⁴ *Microfinancial, Inc.*, 385 F.3d at 77.

⁶⁵ Dkt. 2209, p. 6, n. 9 ("It appears that no order entered in the MDL to date would prohibit the criminal defendants' participation in, or access to, the depositions").

⁶⁶ Dkt. 1426, §E.

The criminal defendants, who have been dismissed from the cases and are no longer parties, do not meet any of these categories. Thus, contrary to the Government's statement, the criminal defendants would not be allowed to attend or participate in the depositions.

Further, the litigation has a protective order in place that allows any deposition testimony to be designated "confidential,"⁶⁷ which is then sealed (along with any documents designated confidential) under the order⁶⁸. And, regardless, what information will the criminal defendants learn that they do not already know?⁶⁹

The Government also offers little of substance to support the argument that the depositions of former NECC and MSM employees will impact the criminal defendants' right to a fair trial.⁷⁰ The Government makes the conclusive statement that the civil depositions "could" generate pretrial publicity and "could" affect a fair trial, but does not explain how.⁷¹ "Could" does not clear the hurdle of a "heavy burden."

⁶⁷ Dkt. 814.

⁶⁸ Dkt. 1426, §E.

⁶⁹ The Government mentions in its brief that criminal defendants can take advantage of the more liberal discovery rules in civil cases, to their advantage in the criminal case. While that general proposition may be true, the inverse is true here. The parties to the criminal action have exchanged millions more documents than NECC has produced in the civil litigation. As documented early in this brief, NECC, its employees, and its affiliates have all refused to participate in discovery.

⁷⁰ If anyone should be worried about pretrial publicity causing an unfair trial, it should be the criminal defendants. It is telling that they have not moved for a stay of the civil case. Regardless, if the Government were really worried about tainting the jury pool, it would not have convicted the criminal defendants by press release following the indictment. ("[T]hese employees knew they were producing their medication in an unsafe manner and in insanitary conditions, and authorized it to be shipped out anyway, with fatal results." "Actions like the ones alleged in this case display not only a reckless disregard for health and safety regulations, but also an extreme and appalling indifference to human life." "When people and companies violate that trust and break the law, the consequences to patients and their families can be catastrophic.") (press release at: <http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis>).

⁷¹ Dkt. 2209, p. 2, 14.

The Government also makes no particularized argument about which depositions truly need to be stayed to protect the sanctity of the criminal prosecution. The Government asks for a general stay of all discovery of NECC or MSM employees. A more specific approach should be favored, as the Government concedes.⁷²

Lastly, the Government offers no case law to support a stay in this situation. It cites the same case twice (*TelexFree*). That case is a non-starter because the parties *agreed* to the stay. *Zavatsky*⁷³ offers little guidance as it does not involve a situation where a civil party is potentially being forced to trial without necessary discovery because of the stay.

* * * * *

If the Court intends to push the Tennessee Clinic Defendants into expert discovery and trial before the criminal trial, the equities weigh against the stay of discovery of the NECC/MSM employees. Their testimony is necessary to the civil trials. When considered in that context, the Government has not met its heavy burden to justify the stay.

However, the Tennessee Clinic Defendants maintain that the most reasonable course is to stay the NECC/MSM depositions, expert disclosure deadlines, and civil trial pending completion of the criminal case.

⁷² Dkt. 2209, p. 13-14.

4. Conclusion

The Tennessee Clinic Defendants cannot fairly defend the civil complaints against them without the depositions of NECC and MSM employees. The testimony is indispensable on issues like the standard due diligence required before purchasing from NECC and whether NECC's conduct was an intervening cause of the Plaintiffs' injuries. It is also highly relevant to the comparative fault of NECC/MSM.

Because the testimony is necessary for defense of the civil cases, the Court cannot stay the depositions unless the MDL expert deadlines and civil trial date are also stayed until the criminal case concludes. While the NECC/MSM-related discovery is stayed, the parties can continue with document discovery and non-NECC/MSM related discovery. Once the criminal trial concludes, the parties can conduct the depositions of the NECC/MSM witnesses and try the first civil case.

In the alternative, if the Court intends to press the Tennessee Defendants into expert discovery and trial prior to the criminal case concluding, the equities mandate that the Government's Motion be denied.

Finally, the Court has already ruled that the MA BoP deposition can go forward. There is no reason to revisit that ruling now, as the Government has raised no new reason for it to be stayed.

* * * * *

The Tennessee Clinic Defendants respectfully request that the Court enter the proposed order attached as Exhibit 1.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 28th day of September, 2015.

/s/ Chris J. Tardio

Chris J. Tardio